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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,179	DE GRAAF ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-14,16-38,71,72 and 75-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-14,16-38,71,72 and 75-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Workgroup 1630, Art Unit 1634, and has been docketed to Primary Examiner Bradley L. Sisson.

Specification

2. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. In the instant case, the aspect of a "publication" has been construed to include electronic databases that have been made available to paying customers.

3. In is noted with particularity that the claimed method requires *inter alia*, for the skilled artisan to select "at least three informative nucleic acid molecules" (also described as "informative genes") from among the molecules in Figures 1A-U. A review of Figures 1A-U does not find any nucleic acid sequence, but does find reference to accession numbers, which at page 6, line 27, is defined as "Affymetrix annotation." It is without doubt that these nucleic acids are essential to practicing the claimed method. A review of the disclosure fails to find where applicant has explicitly stated that they seek to incorporate by reference these disclosures of nucleic acids. Accordingly, while applicant has made reference to these documents or disclosures, such general teachings do not constitute a proper incorporation by reference for which applicant could thereby bring into the present disclosure such essential subject matter.

Therefore, applicant's referencing "Affymetrix annotations" has been considered without effect towards fulfillment of the written description, enablement, or best mode requirements of 35 USC 112, first paragraph.

4. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification contains statements that certain published documents have been incorporated by reference "in their entirety" (see page 14, lines 20-23; page 20, lines 2-4 and 24-27). While applicant has sought to incorporate such documents "in their entirety," such omnibus language lacks the requisite "detailed specificity" as to where the sought material is actually found in each of the documents. Such language has not been considered to constitute a proper incorporation by reference. While the cited documents may be relied upon for background, they have not been considered properly incorporated by reference and have not been considered to fulfill either in full or in part, the written description, enablement, or best mode requirements of 35 USC 112, first paragraph. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USPQ 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a

part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3-14, 16-38, 71-72, and 75-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

7. For convenience, claims 1, 14, 20, 33, 71, 72, 75, and 87, the only independent claims, are reproduced below.

Claim 1. A method of identifying an upper intestinal polyp or a colonic polyp comprising the step of:
a) determining an expression profile from expression products in a nucleic acid sample derived from intestinal tissue, of at least three informative nucleic acid molecules having increased expression in an upper intestinal polyp or a colonic polyp relative to a control,
wherein increased expression of said nucleic acid molecules in said sample is indicative of an upper intestinal polyp or a colonic polyp.

Claim 14. A method of identifying an upper intestinal polyp or a colonic polyp comprising the step of:
a) determining an expression profile from expression products in a polypeptide sample derived from an intestinal tissue of at least three informative nucleic acid molecules having increased expression in an upper intestinal polyp or a colonic polyp relative to a control,
wherein increased expression of said nucleic acid molecules in said sample is indicative of an upper polyp or a colonic polyp.

Claim 20. A method of identifying an intestinal polyp comprising the step of:
a) determining an expression profile from an expression product in a nucleic acid sample derived from intestinal tissue of at least one informative nucleic acid molecule having decreased expression in an intestinal polyp relative to a control,
wherein decreased expression of said nucleic acid molecule in said sample is indicative of an intestinal polyp.

Claim 33. A method of identifying an intestinal polyp comprising the step of:
a) determining an expression profile from an expression product in a polypeptide sample derived from intestinal tissue of at least one informative nucleic acid molecule having decreased expression in an intestinal polyp relative to a control,
wherein decreased expression of said nucleic acid molecule in said sample is indicative of an intestinal polyp.

Claim 71. A method of identifying an upper intestinal polyp or a colonic polyp comprising the step of:
a) determining an expression profile from a expression product in a nucleic acid sample derived from intestinal tissue of at least one informative nucleic acid molecule having increased expression in an upper intestinal polyp or a colonic polyp relative to a control, wherein said informative nucleic acid molecule is selected from the group consisting of the nucleic acid molecules in Figures 1A-1U,
wherein increased expression of said nuclei acid molecule in said sample is indicative of an upper intestinal polyp or a colonic polyp.

Claim 72. A method of identifying an upper polyp or a colonic polyp comprising the step of:
a) determining an expression profile from an expression product in a polypeptide sample derived from intestinal tissue of at least one informative nucleic acid molecule having increased expression in an upper intestinal polyp or a colonic polyp relative to a control, wherein said informative nucleic acid molecule is selected from the group consisting of the nucleic acid molecules in Figures 1A-1U,
wherein increased expression of said nucleic acid molecule in said sample is indicative of an upper intestinal polyp of a colonic polyp.

Claim 75. A method of identifying an intestinal polyp comprising the step of:
a) determining an expression profile, from expression products in a nucleic acid sample derived from upper intestinal tissue or colonic tissue, of at least three informative nucleic acid molecules having increased expression in an intestinal polyp relative to a control,
wherein increased expression of said nucleic acid molecules in said sample is indicative of an intestinal polyp.

Claim 87. A method of identifying intestinal polyp comprising the step of:
a) determining an expression profile, from expression products in a polypeptide sample derived from upper intestinal tissue or colonic tissue, of at least three informative nucleic acid molecules having increased expression in an intestinal polyp relative to a control,
wherein increased expression of said nucleic acid molecules in said sample is indicative of an intestinal polyp.

8. For purposes of examination, the claims have been interpreted as encompassing identifying upper intestinal polyps and lower intestinal polyps in any sample of intestinal tissue, including the detection of colonic polyps when the tissue is taken from an upper intestinal region, e.g., duodenum, jejunum, ileum, or appendix, as well as when the intestinal tissue is taken from the ascending or transverse colon when the polyp is located in the sigmoid colon.

9. Said method claims have also been interpreted as encompassing distinguishing between upper and lower intestinal polyps using the same one, or three informative nucleic acid molecules or informative genes.

10. Said claims have been interpreted as encompassing the detection the detection of said intestinal polyps when the "intestinal tissue" is that taken from the intestine via biopsy, as well as from the surface of fecal material.

11. Said method claims have been interpreted as encompassing the detection, identification and discrimination of upper and lower intestinal polyps as found in any life form provided that the life form has an intestine. Such life forms include, but are not limited to humans, monkeys, apes, horses, sheep, canines, pigs, antelope, whales, dolphins, lions, tigers, puma, cattle, buffalo, bison, oxen, fish, amphibians, reptiles, bats, mice, birds, and rats.

12. As an initial matter, the claims are rejected as a result of containing new mater. As filed, the specification and claims were directed to methods where one is performing the requisite identification based on "informative genes." The claims have been amended so to reflect that one is no longer using "informative genes" but rather, "informative nucleic acid molecules." A review of the disclosure fails to locate support for "informative nucleic acid molecules." Applicant is urged to consider amending the claims such that they no longer contain new matter.

13. Assuming *arguendo*, that applicant amends the claims such that they recite "informative gene," a review of the disclosure fails to find an adequate written description of such "informative genes." For purposes of examination, a "gene" has been interpreted as comprising regulatory sequences, promoter regions, exons and introns. While column 1 of Figure 1A states "Genes present in at least 4 'normal' tissues, two each upper and lower intestine, absent in polyps," it is clearly evident that the "genes" listed are not in fact genes, as the first "gene" listed is that of a cDNA molecule. Given that a cDNA is a copy DNA molecule of a messenger RNA (mRNA) molecule, it lacks the regulatory sequences, promoter(s) and introns.

14. To the extent that Figures 1A-1U do list numerous sequences by name, the Figures do not have been found at best a description of how the encoded polypeptide is to function, not a description of either the nucleic acid or of the amino acid encoded thereby. Indeed, numerous "sequences" are of an EST, or expressed sequence tag, for which no one function exists, including a definitive amino acid sequence encoded hereby, its function.

15. As seen above, numerous claims require the identification to be predicated on the presence of a polypeptide, and as seen in claims 17, 30, 36, 84, and 89 one is to use antibodies. Not knowing the amino acid sequence and more particularly the antigenic determinants of the encoded polypeptide, one cannot produce a polypeptide that binds specifically to the intended target. A review of the disclosure fails to find an adequate written description of the requisite antibodies and as such, the specification does not reasonably suggest that applicant possessed the requisite starting materials needed for practicing the claimed method.

16. Similarly, claims 6, 7, 25, 26, 79, and 80 require the use of "specific hybridization probes." And in claims 8, 9, 27, 28, 81 and 82 one is to use "oligonucleotide microarrays" yet the specification does not provide an adequate written description of the required multiple arrays. A review of the disclosure fails to find an adequate written description of the innumerable "specific hybridization probes" and "oligonucleotide microarrays" as well as a detailed description of how they are to be used.

17. In claims 12, 18, 31, 37, 85, and 90 one is to perform the method wherein the informative nucleic acid molecules are selected from "apoptosis genes, cell cycle genes, tumor suppressor genes, cell adhesion genes, transcription genes, and inflammation genes" as found in any life form that has an intestine. As noted above, the specification does not provide an adequate

written description of any gene, much less each of the above-required genes in any organism, much less an adequate written description of these genes, pro4es, and related oligonucleotide microarrays as they relate to any and all possible life forms. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

18. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 3-14, 16-38, 71-72, and 75-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

19. Claims 1, 3-14, 16-38, 71-72, and 75-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513

> (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

20. It is well settled that one cannot enable an invention that they do not yet possess. As set forth above, the specification has not been found to provide an adequate written description of the invention so to reasonably suggest that applicant had possession of same at the time of filing. Accordingly claims 1, 3-14, 16-38, 71-72, and 75-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

21. In addition to requiring the specification to enable that which applicant possessed, the specification must also set forth the required starting materials and reaction conditions in order to enable the claimed methods. To do otherwise would require undue experimentation on the part of the public. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue

experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').

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"Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
"It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

22. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 3-14, 16-38, 71-72, and 75-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

23. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

24. Claims 1, 3-14, 16-38, 71-72, and 75-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

25. Claims 1, 3-14, 16-38, 71-72, and 75-91 are indefinite with respect to what constitutes "informative nucleic acid molecules."

26. Claims 4, 23, and 77 are indefinite with respect to how DNA is an "expression product." While DNA may be transcribed so to yield mRNA, and that mRNA may be translated so to yield, or "express" a protein, it is unclear how DNA is an expression product.

27. Claims 13, 19, 32, 38, and 71-91 are confusing as to how the method is to be practiced when the artisan is required to use "informative nucleic acid acids" and when said "informative nucleic acid molecules" are to be selected from any nucleic acid molecules in Figures 1QA-1U, yet Figures 1A-1U clearly identify control (non-informative) nucleic acid molecules.

Conclusion

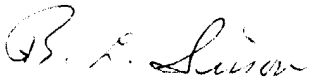
28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. US Patent Application Publication 2004/0002591 A1, paragraph 415, teaches a method of detecting "tumors of the colon (e.g., polyps or cancers) ... [and] benign tumors of the duodenum" wherein said diagnosis is predicated on the sue of proteins, nuclei acids or antibodies.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
05 April 2004